Reporting Limit (RL)

Presenter

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Purpose

- What is Reporting Limit (RL)?
- Why is RL needed?
- How is RL established?
- Applications and case study
- Major issues
- Summary

Introduction

- **Reporting Limit (RL) is widely used but not clearly defined. For example:**
  - **RL – the minimum value below which data are documented as non-detects – EPA OW, Office of Resource Conservation and Recovery (ORCR), and Office of Enforcement and Compliance Assurance (OECA)**
  - **RL – the minimum value of the calibration range. Analyte detections between the detection limit and the reporting limit are reported as estimated – EPA ORD and ORCR**
  - **RL > MDL and the client and/or data-users determine RL – California Department of Health**
- **Many projects improperly set RL at contract lab's LOQ**

RL in DoD QSM

- **DoD QSM Version 4.2:**
  - **RL – a client-specified lowest concentration value that meets project requirements for quantitative data with known precision and bias for a specific analyte in a specific matrix**
  - **RL = Client-specified quantitation limit that meets project data quality needs**
  - **RL is clearly defined in the DoD QSM but …….**

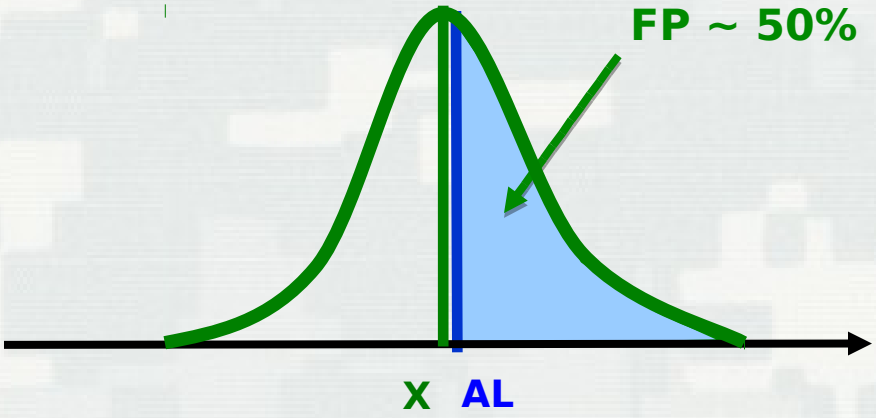
    ……. without determination procedure

Project-Specific RL

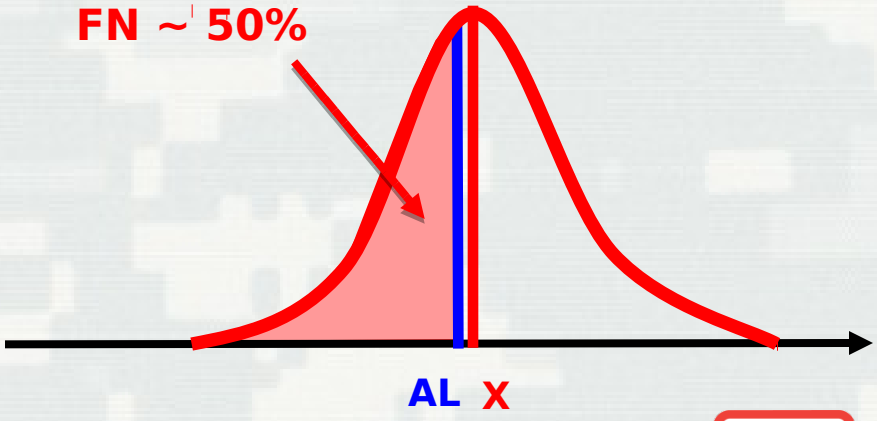
- **Why is a Project-Specific RL needed?**
  - **To reliably determine if a site is CLEAN**
    - ✓ **CLEAN: [X] < Regulatory Level, Background Level, Risk-Based Level, etc., i.e., Action Level (AL)**
    - ✓ **Procedure: comparison of [X], mean, etc. with AL**
    - ✓ **Need to determine or estimate true analyte concentration with uncertainty at Project-Specific RL (i.e., Decision Level)**
  - **To select analytical methods and labs**

May RL = AL?

- To reliably determine if a site is clean, one needs to determine if [X] ≤ AL
- Problems with RL = AL



True [X] < AL



True [X] > AL

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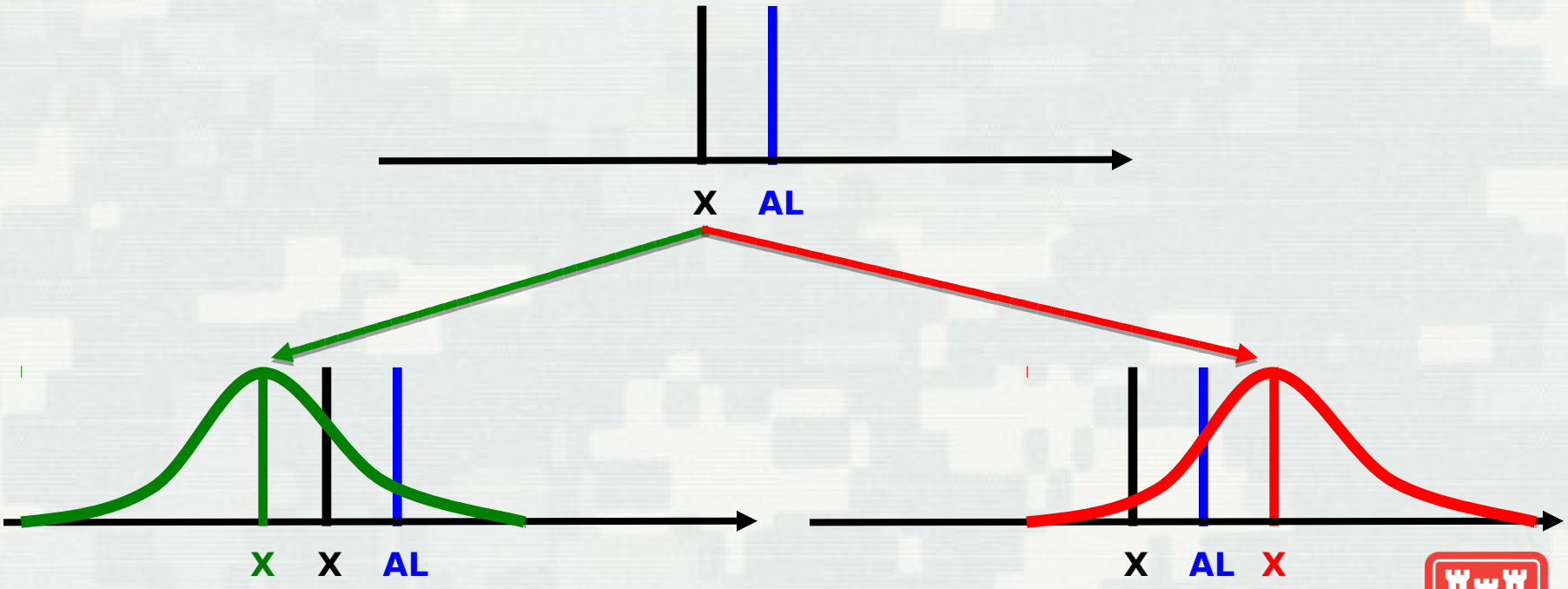
Is [X] < AL?

- **Is [X] < AL? [X] = single/multi-measurements**



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Need Quantitation at RL < AL

- To determine if [X] < AL, one needs to quantify [X] at Project-Specific RL
- Project-Specific RL depends on:
  - AL (regulatory level, background, risk-based, etc.)
  - Data Quality (precision & bias)
  - Tolerable Decision Errors (FP/FN, Type I/II)
- RL < AL but how much lower depends on Data Quality and Tolerable Decision Errors

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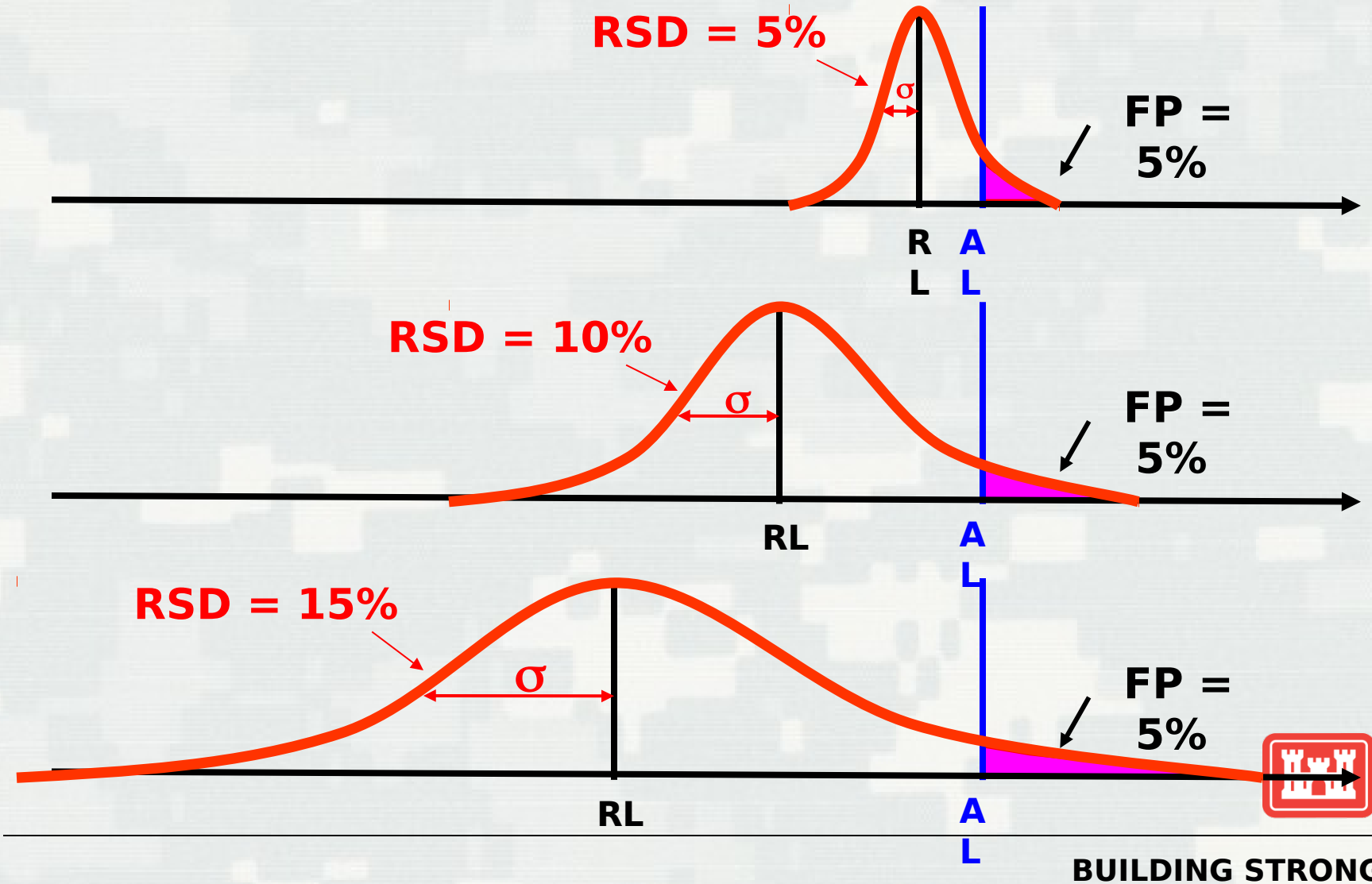
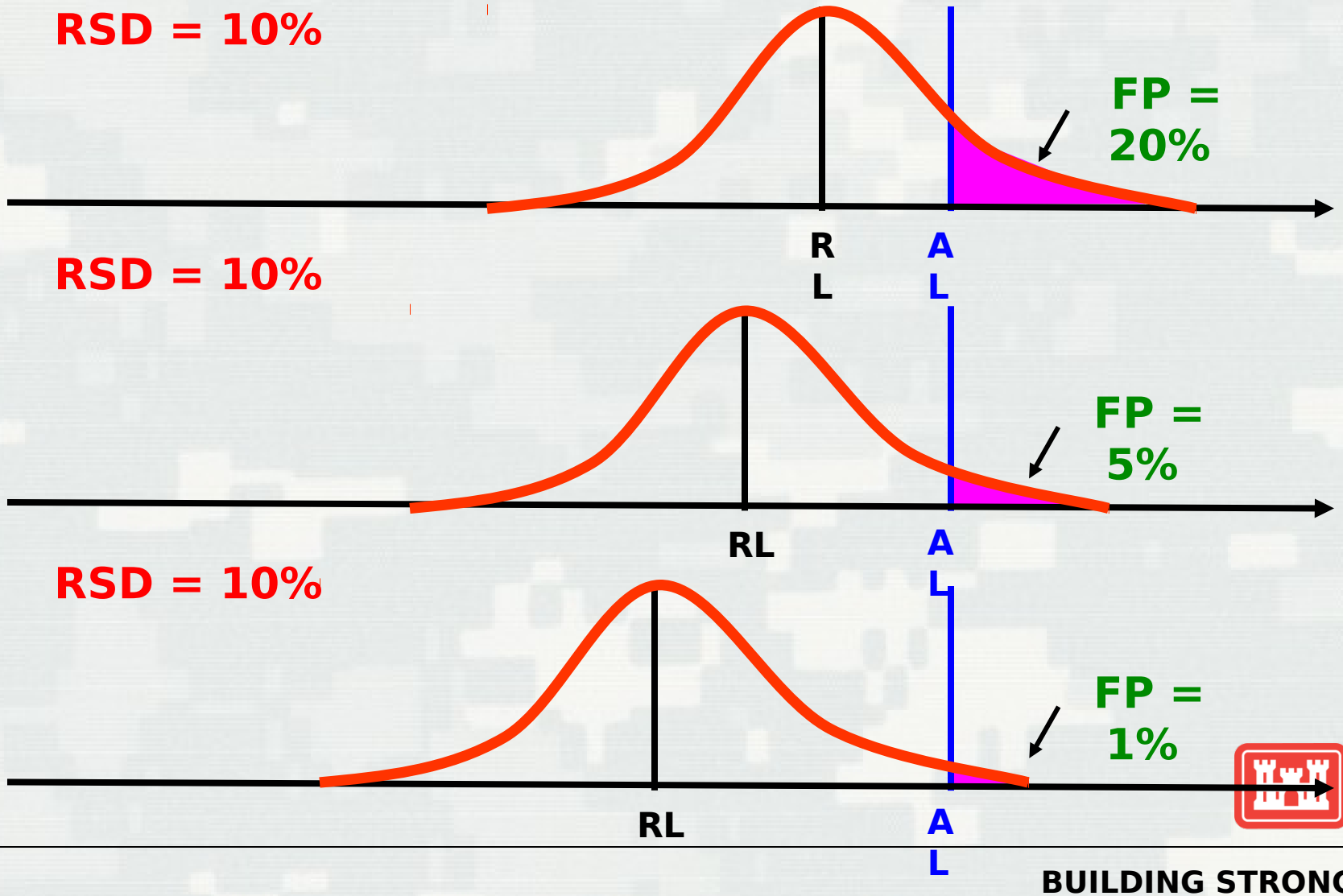
Data Quality – Precision



Tolerable Decision Error – FP



RL vs. AL, DQ, & TDE

- **Project-Specific RL depends on:**
  - **RL < AL**
  - **RL ↓ if Data Quality (DQ) ↓**
  - **RL ↓ if Tolerable Decision Errors (TDE) ↓**
- **How to establish a Project-Specific RL?**

How's RL Commonly Established?

- RL = Lab's LOQ (~ 80% projects)
- RL = Lab's MDL
- RL = Regulatory Limit
- RL = AL
- RL = ½ AL
- RL = 3 – 5 times less than AL

Common Reasons for Lack of Project-Specific RL

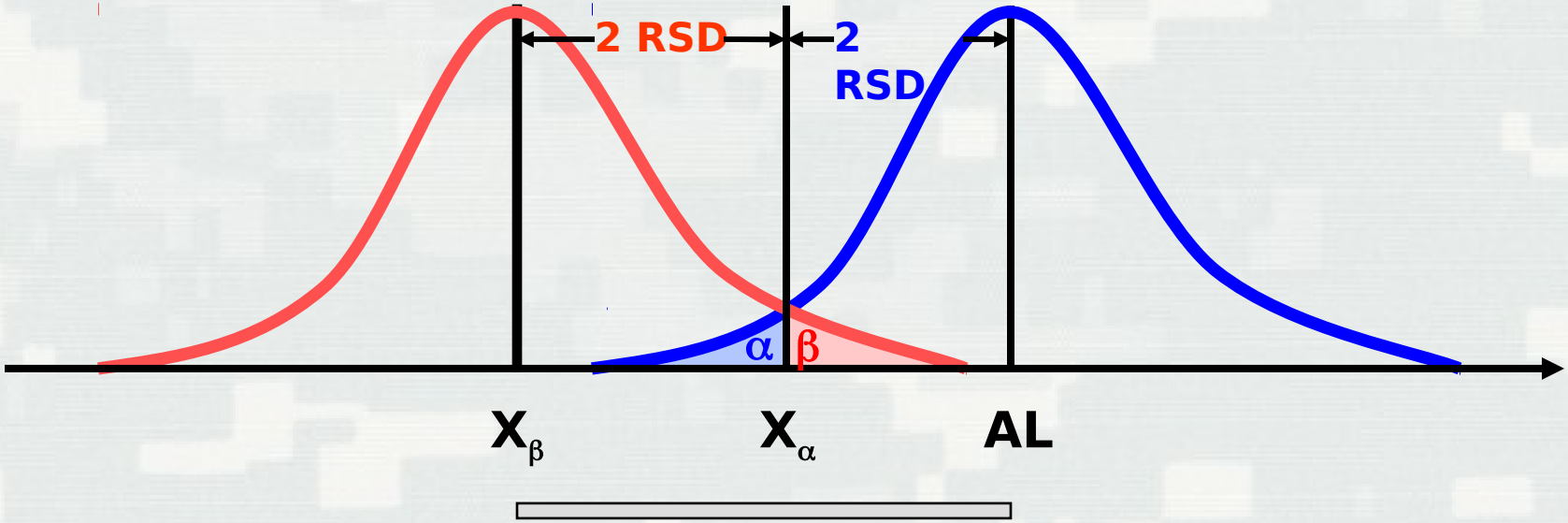
- Don’t know how
- Unknown data quality before analysis
- Huge field sampling errors
- Risk assessor establishes
  - PMs believe RL in number is adequate
- Limited resources
- Pandora’s box

Inputs for Establishing Project-Specific RL

- **Action Level (AL): Regulatory level, background level, risk-based level, etc.**
- **Anticipated Data Quality: Based on DQOs, historical data, method, publication, etc.**
- **Tolerable Decision Errors: Type I/II (α/β) or FP/FN (Default $\alpha = \beta = 0.05$ or FP = FN = 5%)**

Procedure for Establishing RL

H_O: X > AL, H_A: X ≤ AL; decision errors α = β = 0.05



Δ = k × RSD × AL

RL ≤ (AL – Δ) × %R = (AL – k × RSD × AL) × %R, where

k = Error Factor, RSD = Rel Std Dev, %R = Recovery

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Determine n, RSD, & %R

- $RL \leq (AL - k \times RSD \times AL) \times \%R$
  - $k = 4$ if FP = FN = 5% (2 RSD + 2 RSD)
  - $k = 5$ if FP = 1% (3 RSD) & FN = 5% (2 RSD)
  - $k = 6$ if FP = FN = 1% (3 RSD + 3 RSD)
- $RSD \leq [1 - RL / (AL \times \%R)] / k$
  - If $k = 4$, RSD must be < 25%
  - If $k = 5$, RSD must be < 20%
  - If $k = 6$, RSD must be < 17%

k is based on tolerable decision errors
RSD & %R are data quality indicators at RL

Determine AL, DQ, & TDEs

- **Action Level (AL): Regulatory level, background, risk-based level, etc.**
- **Anticipated Data Quality: Based on DQOs, historical data, method, publication, etc.**
  - **Historical data**
  - **DoD QSM LCS Control Limits**
  - **Technology capabilities**
- **Tolerable Decision Errors: Type I/II (α/β)**
  - **Regulations**
  - **Practicality**
  - **Resources**

Applications of RL

- **Select analytical methods**
  - **RL vs. method performance**
- **Select analytical labs**
  - **RL vs. lab performance**
- **Assess data quality**
  - **Lab LOQ vs. project RL (LOQ ≤ RL if compatible precision and bias)**
- **Assess data usability**
  - **Lab LOQ vs. project RL and AL (LOQ ≤ RL < AL if compatible precision and bias)**

Case Study of Project-Specific RL

- **Investigate ground water contamination by benzo(a)pyrene**
  - **Establish RL and associated precision & bias**
  - **Select analytical method & contract lab**
- **Inputs:**
  - **AL: 0.2 ppb (MCL)**
  - **Anticipated Data Quality: RSD = 9.5% & %R = 81% (DoD QSM LCS)**
  - **Tolerable Decision Errors: FP = FN = 5%**
- **RL ≤ (AL – 4 × RSD × AL) × %R = 0.10 ppb**
  - **if RSD ≤ 9.5% & %R ≥ 81%**

Case Study of Method & Lab Selections

- **LOQ ≤ RL ≤ (AL – 4 × RSD × AL) × %R = 0.10 ppb**

  if AL = 0.2 ppb, RSD ≤ 9.5% & %R ≥ 81%

- **DoD ELAP accredited Lab X:**

  ➢ **SW 8270: LOQ = 0.2 ppb, RSD = 16.2% & %R = 82.5%**

  (Ideally, LOQ ≤ (0.2 – 4 × 16.2% × 0.2) × 82.5% = 0.058 ppb)

- **DoD ELAP accredited Lab Y:**

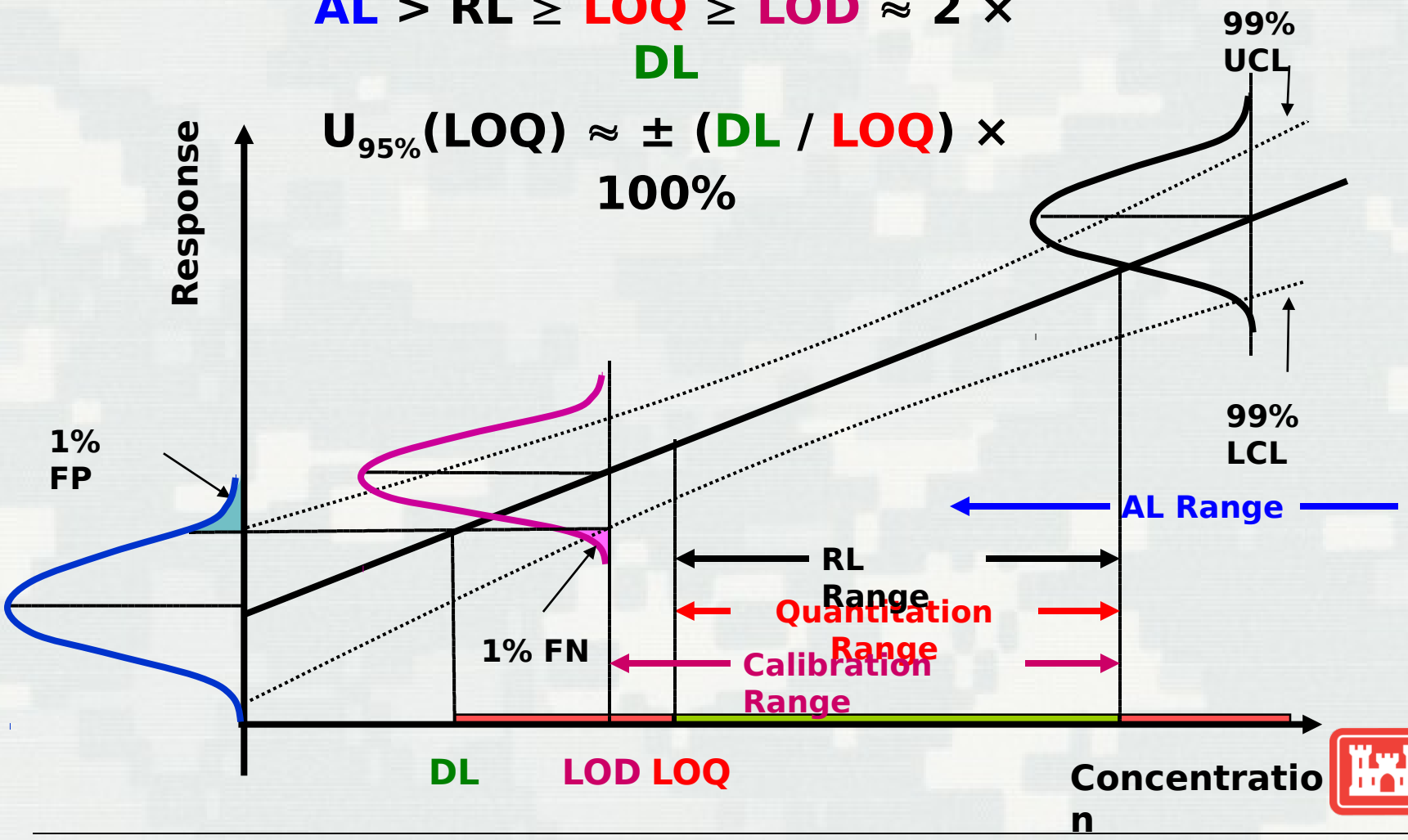
  ➢ **SW 8270: LOQ = 0.2 ppb, RSD = 9.8% & %R = 84.5%**

  ➢ **SW 8310: LOQ = 0.1 ppb, RSD = 9.5% & %R = 92.5%**

Relationships among Various Limits

AL > RL ≥ LOQ ≥ LOD ≈ 2 × DL

$$U_{95\%}(LOQ) \approx \pm (DL / LOQ) \times 100\%$$



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Major Issues

1. Old Rule of Thumb, RL = 1/2 ~ 1/5 AL, may not be adequate
2. LOQ ≤ RL is neither necessary nor sufficient; lower LOQ is not necessary better – must consider precision & bias at LOQ and RL
3. RL based on precision & bias of clean matrix spikes is a minimum RL
4. Safety factors built in AL or risk assessment do not take care of decision errors
5. Huge field sampling errors trump lab analysis errors

Major Issue # 1

Old Rule of Thumb, RL = 1/2 ~ 1/5 AL, may not be adequate

If AL = 100, is RL = 50 ~ 20 adequate?

- **Ideal SW-846 default, LCS CL = 70 – 130% (RSD = 10% & %R = 100%) and $\alpha = \beta = 0.05$ (k = 4)**

  $RL \leq (AL - k \times RSD \times AL) \times \%R$

  $\leq (100 - 4 \times 10\% \times 100) \times 100\% = 60$

  1/2 ~ 1/5 AL = 50 ~ 20 < 60 ✓

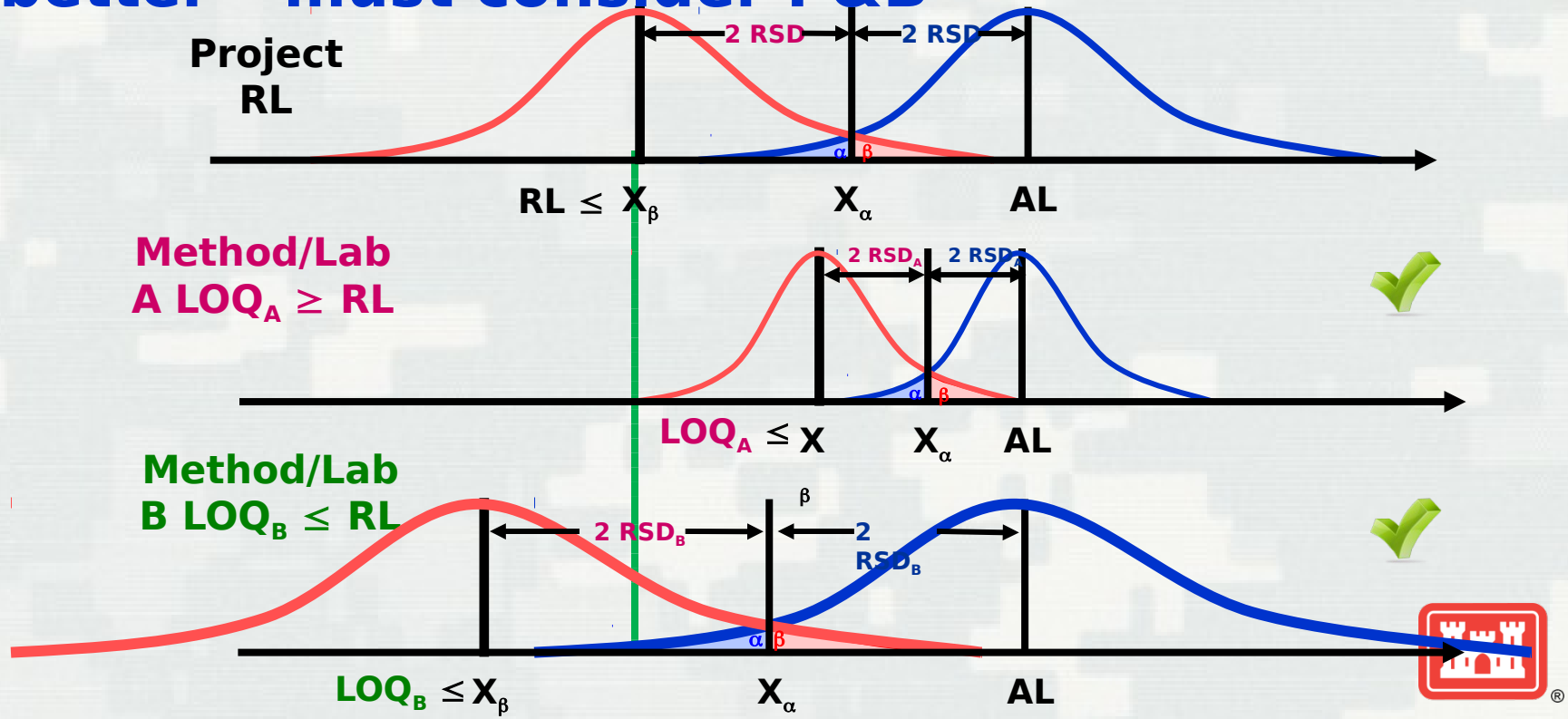
- **If LCS CL = 20 – 80% (RSD = 10% & %R = 50%)**

  $RL \leq (100 - 4 \times 10\% \times 100) \times 50\% = 30$

  1/2 AL = 50 > 30 ✗ **1/5 AL = 20 < 30** ✓

Major Issue # 2

LOQ ≤ RL is neither necessary nor sufficient; Lower LOQ is not necessary better – must consider P&B



Major Issue # 3

RL based on precision & bias of clean matrix spikes is a minimum RL

- Precision & bias based on clean matrix spikes such as method performance data, DoD QSM, or lab's LCS do not include matrix interferences
- A common denominator approach similar to DL, QL, and LCS studies for data comparability
- Because individual matrices are different, matrix-specific precision & bias cannot be reliably and cost-effectively estimated prior to sample analysis
- Matrix interferences may be assessed upon sample receipt or based on MS/MSD

Major Issue # 4

Safety factors built in AL or risk assessment do not take care of decision errors

- To have or not to have corrective action generally depends on the data quality and tolerable decision errors at the AL, not the accuracy of the AL
- Safety factors may not affect the decision rule, e.g., if [X] > AL, clean site; if [X] ≤ AL, dirty site
- To reliably determine if [X] > AL, one needs to quantify and make the decision at RL

Major Issue # 5

Huge field sampling errors trump lab analysis errors

- **Lab shall meet project MQOs, not DQOs. Lab is not liable for sampling errors and can't compensate large sampling uncertainty (Typical lab RSD must be < 25%)**
- **Field sampling uncertainty cannot be reliably estimated without site investigation and is typically > 4x lab uncertainty**
- **Lab performance yardsticks, method performance data, do not include field sampling uncertainty**
- **Need better sampling techniques (e.g., MIS) to reduce and control field sampling errors prior to evaluating field sampling uncertainty**

Summary

- **A simple, reliable, and practical procedure for establishing RL based on project-specific AL, anticipated data quality, and tolerable decision errors**
- **RL established based on precision and bias of clean matrix spikes is a minimum RL. More stringent RL is needed to cover sample matrix interferences and field sampling errors**
- **A useful tool for project planning, selecting analytical methods and contract labs prior to contract award**
- **LOQ ≤ RL < AL may not meet project DQOs**

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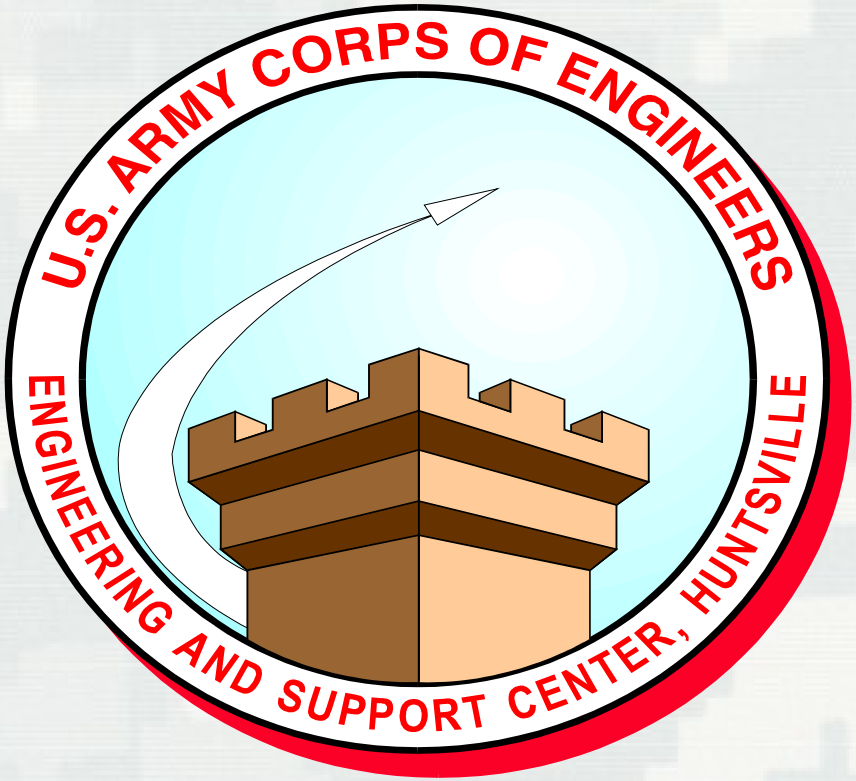
Questions?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